

#### REMARKS

As an initial matter, the undersigned thanks Examiner Alexander for the courtesies extended during the personal interview that was conducted on June 4, 2009. During that interview, U.S. Patent No. 4,014,322 to Shah ("the Shah reference") was discussed, as well as claim language that could distinguish from the teachings of the Shah reference. In particular, Applicants' representatives and the Examiner discussed how claim language reciting a collector portion second end moveable relative to a handle portion when a collector portion first end is coupled to the handle portion second end could distinguish from the Shah reference. Also, during the interview, Applicants' representatives and the Examiner discussed how claim language reciting a sponge having a dry size, as well as first and second collection sizes holding sample sufficient for assay could distinguish over the Shah reference. During the interview, the Examiner also suggested that readability of at least some of the claims might be improved by making amendments to reorganize where in the claims some of the elements are recited; such amendments not being related to patentability.

Claims 1, 4, 6, 7, 12-23, 25, 46-52, 73-75, and 77 are now pending in the application. Claims 2, 3, 5, 8-11, 24, 26-45, 53-72, 76, and 78 have been canceled without prejudice or disclaimer. Claims 1, 7, 12-22, 25, 46, 49-52, 73, 75, and 77 have been amended. It is believed that the amendments to the claims reflect the agreements reached during the interview. Support for the claim amendments may be found throughout the original specification and claims. No new matter has been added.

At page 2 of the Office Action, claims 1, 2, 4, 6, 7, 9, 12-23, 25, 46-52, and 73-76 were rejected under 35 U.S.C. § 102(b) "as being clearly anticipated by" the Shah reference, and claim 77 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Shah reference.

In making the rejections based on the Shah reference, the outstanding Office Action refers to the rejection set forth in the Office Action dated October 2, 2007, which asserted, among other things, that Shah teaches that "[a]bsorbent/sponge(56) has a first size prior to sample application where it is the width of slot(52) and a second larger size when the sample is applied that is larger than the distance between slot(52) and slot(54)." (See Office Action dated October 2, 2007, p. 2). Further, at page 3, the outstanding Office Action dated February 9, 2009, asserts that "Shah teaches in column 4, lines 30-34 [that] slot(52) [sic] retains the sponge(56) in a compressed configuration and this compressed configuration is what the Office intended by a 'first size(52).'"

Each of independent claims 1, 46, 73, and 77 is directed to a sample collection device for assay and, as amended, each recites, *inter alia*, a "sponge disposed on the collector portion and having a dry

size, a first collection size when the sponge holds a first amount of sample and a second collection size when the sponge holds a second amount of sample." Independent claim 1 further recites that "sufficient sample is collected for assay when the sponge second collection size is substantially equal to the collector portion extended size" and that "placing the sponge in the first collection size . . . retain[s] a second portion of sample in said sponge for subsequent assay." Independent claim 46 further recites that "the second amount of sample is sufficient for a first assay of sample and the first amount of sample is sufficient for a second assay of the sample subsequent to the first assay." Independent claims 73 and 77 each additionally recites "the first amount of sample being sufficient for assay" and "a sufficient sample is collected for assay when the sponge second collection size is substantially equal to the collector portion extended size."

Thus, each of independent claims 1, 46, 73, and 77 recites a sponge with a dry size and first and second collection sizes, wherein each of the first and second collection sizes holds respective amounts of sample sufficient for assay. As discussed during the interview, the Shah reference does not disclose a sponge having first and second collection sizes with each holding an amount of sample sufficient for assay. Rather, the Shah reference discloses a sponge 56 that has a dry size when compressed in the slot 52, as depicted in FIGS. 1 and 2, and a single collection size shown in FIG. 3. As shown in FIG. 4, Shah teaches compressing the sponge 56 to release sample from the sponge 56 to be collected in the container chamber 28. More specifically, referring to column 3, lines 30-42, the Shah reference states teaches:

*Before wetting*, the diameter of the bore 58 [of the sponge 56] is preferably of a size less than the outside diameter of the shaft 40 adjacent the slot 52, while the thickness of the sponge 56 is preferably of a size approximately equal to the width of the slot 52, such that the unwetted sponge 56 is retained in position on the shaft 40 in the slot 52. *When wetted*, the sponge 56 expands both laterally and longitudinally relative the shaft 40, such that lateral expansion of the sponge 56 enlarges the bore 58 to a diameter size greater than the outside diameter of the shaft 40, thus permitting expansion of the sponge 56 longitudinally along the shaft 40, as shown in FIG. 3. ...

The Shah reference further states at column 4, lines 18-33:

With reference to FIG. 4, after the lid 34 has been secured to the container 22, the shaft 40 may be moved outwardly through the lid aperture 38 to reduce the spacing between the plate and lid, *such that the wetted sponge 56 is compressed between the plate 50 and the lid 34 to release the sample* in an aseptic manner into a lower part of the container chamber 28. Referring to FIG. 5, as the shaft 40 moves through the lid, the relatively small second slot 54 passes through the lid aperture 38, after which the first slot 52 receives the lid 34 and stops movement of the shaft at a second outer position of the shaft *when the specimen has been substantially*

***compressed from the sponge 56.*** The interengaged lid 34 and slot 52 subsequently retain the sponge in its compressed configuration intermediate the plate 50 and lid 34.

Thus, the Shah reference teaches an unwetted size of the sponge 56 and a single, wetted collection size of the sponge 56. As discussed during the interview, rather than teaching another collection size of the sponge 56 other than the wetted size of FIG. 3, the Shah reference teaches compressing the sponge 56 between the plate 50 and the lid 34 to release the sample from the sponge 56 until the specimen has been substantially compressed from the sponge 56. Nowhere does the Shah reference disclose or otherwise suggest that the sponge 56 has another collection size other than the one depicted and discussed with reference to FIG. 3 that holds an amount of sample for assay. For at least this reason, independent claims 1, 46, 73, and 77 are patentably distinguishable from the Shah reference.

Moreover, independent claim 1 recites a "collector portion first end detachably coupled to the handle portion second end and the collector portion second end . . . being movable relative to the handle portion second end when the collector portion is coupled to the handle portion." Independent claims 46 and 73 each recites "a collector portion first end being coupled to a handle portion second end and the collector portion second end" "being movable relative to the handle portion second end when the collector portion first end is coupled to the handle portion second end." Independent claim 77 recites that "the collector portion is an elongate member" and that "the handle portion second end defines an opening sized for slidably receiving the elongate member."

As discussed during the interview, in the claim rejections based on the Shah reference, the Examiner equated outer portion 48 of shaft 40 of the Shah reference with Applicants' claimed "handle portion." As further discussed during the interview, with reference in particular to FIG. 3, the Shah reference does not disclose or otherwise suggest that any part of either shaft 40 or the plate 50 is movable relative to the outer portion 48 when the end of shaft 40 at slot 54 is coupled to the outer portion 48. The Shah reference also fails to disclose or otherwise suggest that outer portion 48 or any other portion of shaft 40 defines an opening sized for slidably receiving an elongate member. To the contrary, the Shah reference discloses the outer portion 48 and the remainder of shaft 40 and plate 50 being fixed relative to each other (see in particular FIG. 3) when the outer portion 48 is coupled with the remainder of shaft 40. For at least these additional reasons, therefore, independent claims 1, 46, 73, and 77 are patentably distinguishable from the Shah reference.

For at least the above reasons, independent claims 1, 46, 73, and 77 are patentably

distinguishable from the Shah reference and the Section 102 and 103 rejections based on the Shah reference should be withdrawn. Because claims 4, 6, 7, 9, 12-23, 25, 47-52, 74, and 75 depend either directly or ultimately from one of claims 1, 46, 73 and 77, respectively, those dependent claims are allowable for at least the same reasons as their respective independent claims. In addition, at least some of the dependent claims recite other unique features and/or combinations that are further patentably distinguishable from the art cited in the Office Action, and therefore at least some of those claims also are independently allowable.

The Office Action contains various assertions and/or conclusions regarding Applicants' claims and the cited art with which Applicants do not necessarily concur. Unless expressly noted otherwise, Applicants' silence regarding such assertions and/or conclusions should not necessarily be construed as acquiescence to the same.

In view of the foregoing, Applicants request the withdrawal of the outstanding claim rejections and the timely allowance of the present. Should the Examiner find that any issue remains unresolved, however, or should any new issues arise that could be resolved through discussions with Applicants' representative, then the Examiner is invited to telephone the undersigned at (202) 292-4693 to expedite further prosecution of this application.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees not otherwise accounted for to our Deposit Account No. 50-4126.

Respectfully submitted,

O'BRIEN JONES, PLLC

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